SERIAL NO.09/939 ATTY DOCKET NO. 212345US22CONT U.S. DÉPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE Form PTO 1449 (Modified) **APPLICANT** LIST OF REFERENCES CITED BY APPLICANT FRANKS, ET AL GROUP 1653 FILING DATE (Anticipated) HEREWITH U.S. PATENT DOCUMENTS FILING DATE SUB DOCUMENT **EXAMINER** CLASS NAME DATE IF APPROPRIATE CLASS NUMBER INITIAL 04/26/32 LEO WALLERSTEIN 435 188 1,855,591 AA AB AC AD ΑĘ AF AG AΗ FOREIGN PATENT DOCUMENTS TRANSLATION DOCUMENT COUNTRY DATE YES NUMBER XXX EUROPE EP 0140 489 05/08/85 A.I XXX WO 87/00196 01/15/87 **WIPO** ΑK XXX 03/28/84 UNITED KINGDOM ΑL GB 2 126 588 06/20/84 EUROPE XXX EP 0 111 216 XXX WIPO WO 87/05300 09/11/87 AN XXX 07/17/86 WIPO AO WO 86/04095 XXX WIPO 05/17/90 AΡ WO 90/05182 XXX **EUROPE** 07/29/87 EP 0229 810 B1 AQ XXX EUROPE 01/04/89 AR EP 0 297 887 XXX 07/27/89 WIPO ΆS WO 89/06542 AT ΑU ΑV OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.) The Effect of Sugars on the Thermal Denatation of Lysozyme H7H Uedaira Bull chem Soc  $\underline{53}$  2451 (1980) ΑW Modes of Stabilization of a Protein by Organic Solutes during Desiccation; John F. Carpenter and John H. Crowe, Department of Zoology, University of California, Davis, California Cryobiology 25 pages 459-470 (1988) ΑX Principles of "Cryostabilization" Technology from Structure/Property Relationships of Carbohydrate/Water systems – A Review, Harry Levine and Louise Slade, Nabisco Brands, inc., Corporate Technology Group, Cryoletters 9 pages 21 - 63 The Glassy State and Survival of Anhydrous Biological Systems, Michael J. Burke, pages 358 - 363, (1986) Membranes, Met-bolism, and Dry Organisms. A.C. Leopold, ed. Date Considered \*Examiner: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in

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ATTY DOCKET NO. SERIAL NO. 09 Form PTO 1449 U.S. DEPARTMENT OF COMMERCE 212345US22CONT (DeilipoM) PATENT AND TRADEMARK OFFICE APPLICANT LIST OF REFERENCES CITED BY APPLICANT FRANKS ET AL GROUP 1653 (Anticipated) FILING DATE HEREWITH OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.) Use of Lyoprotectants in the Freeze-Drying of a Model Protein, Ribonuclease, Michael W. Townsend and Patrick P. DeLuca, Journal of Parenteral Science & Technology, 42 pages 190 -199 (1988) Structure and Structure Transitions in Dried Carbohydrate Materials, James M. Flink, Physical Properties of Foods, pages AAB 473 - 521 (1983) Some Physico-Chemical Properties of Lactose, B. L. Herrington, J Dairy Science, 17, pages 501 - 519, (1934) AAC The Glassy State in Certain Sugar-Containing Food Products, G.W. White and S. H. Cakebread, J Food Technol. 1, pages AAD 73-82 (1966) Loss of Structure in Freeze-dried Carbohydrates Solutions: Effect of Temperature, Moisture Content and Composition, Spyros Tsourouflis, James M. Flink, and Marcus Karel, J Sci Fd-Agric 27, pages 509 - 519 (1976) AAE Structural Stability of Intermediate Moisture Foods- A New Understanding, Louise Slade and H. Levine, Food Structure, its Creation and Evaluation, Blanshard and Mitchell, pages 115-180 (1988) AAF The Nature of the Glassy State and the Behavior of Liquids at Low Temperatures, Kauzmann Chem Rev 43, pages 219 -227 (1948) AAG A Polymer Physico-Chemical Approach to the Study of Commercial Starch Hydrolysis Products (SHPs), Harry Levine and Louise Slade, Carbohydrate Polymers, 6 pages 213-244 (1986) Stabilization of Phosphofructokinase during Air-Drying with Sugars and Sugar/Transition Metal Mixtures, John f. Carpenter, Beth Martin, Lois M. Crowe, and John H. Crowe, Cryobiology, 24 pages 455 -464 (1987) Thermostability of Enzyme in the Three-dimensional Network of Polysaccharide Chains, Z. Schneider, A. Stroinski and J. Pawelkiewiz, Bulletin de L'Acad. Polonnaise des Sciences XV1.4, pages 203 and 204 (1968) Preservation of the Enzymatic Activity of Rennin during Spray Drying and During Storage, and the Effect of Sugars and Certain Other Additives, M. J. van de Beek and S. Y. Gerlsma, Neth Mild Dairy J. 23 pages 46 - 5 (1969) The Condense Chemical Dictionary, Seventh Edition, Arthur and Elizabeth Rose, Reinhold Publishing Corporation, page AAL 448 (1961) Walter Relations of Foods, R.B. Duckworth, Editor, Academic Press, page 648 (1975) The New Encyclopedia Britannica, Volume 16, Encyclopedia Britannica, Inc., page 476 - 479 (1985) Hydration-induced Conformational and Flexibility Changes of Lysozyme at Low Water Content, P.L. Poole and J.L. Finney, Int. J. Biol. Macromol., 5 pages 308-310 (1983) Sequential Hydration of a Dry Globular Protein, P.L. Poole and J.L. Finney, Biopolymers, 22 pages 255-260 (1983) Protein Hydration and Enzyme Activity: The Role of Hydration-Induced Conformation and Dynamic changes in the Activity of Lysozyme, J.L. Finney and P.L. Poole, Comments Mol Cell Biophys, 2 pages 129-151 (1984) AAO Date Considered Examiner

\*Examiner: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

ATTY DOCKET NO. U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE Form PTO 1449 (Modified) 212345US22CONT **APPLICANT** FRANKS ET AL LIST OF REFERENCES CITED BY APPLICANT **GROUP** 1653 FILING DATE **HEREWITH** (Anticipated) OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.) Dielectric Studies of Protein Hydration and Hydration-induced Flexibility, Bone and Pethig, J. Mol. Biol., 181 pages 323-326, Production of Trehalose Dried Eggs, Quandrant Experimental Data (not dates) AAS Lyophilization of Biotechnology Products, Arno T. P. Skrabanaja, Andre L. J. De Meere, Rein A. De Ruiter, and Piet J.M. Van Den Detelaar, PDA Journal, 48-6 pages 311-317 (1994) ΆΑΤ Permazyme Tehcnology, Permazyme leaflet (ಗರ್ ರಿವರ್) AAU BioPharm, Roser, Biopharm, pages 49-53, September 1991 Developments in Biological Standardization, Pikal and Sah International Symposium on Biological Product Freeze-Drying and Formulation Bethesda, USA, 74 pages 165-170 (1991) Ready-To-To™ DNA Labeling Kit, Promotional Lecture (Not Jeted) Analects®, Promotional Lecture (Not 1 tel - 1972 or later) Ready-To-To™ Kits for a broad range of Techniques in Molecular Biology, Designed for results - mot surprises, Promotional Lecture (Not dated) PSYCHROMETRIC CHART (not dated) Green and Angell, J. Phys. Chem, 89, 2880 (1989) BAB Another View of Trehalose for Drying and Stabilizing Biological Materials, Levine and Slade, BioPharm, 1992 BAC The Crystalisation of Hydrates From Amorphous Carbohydrates, Barry J. Aldous, Anthony D. Auffret, and Felix Franks, Cryo-Letters, 16 pages 181-186 (1995) BAD Physical Characterization of Spray Dried Sugars Suitable A Carriers in Inhalation Systems, Venkatesh Naini, Peter R. Byron and Elaine M. Phillips, Aerosol Research Group, Poster at Tenth annual AAPS, Miami, FL-PT6180 ROOS - Carbohydrate Research, 238, 38 49 (1993) RAF BAG BAH Date Considered May 24,2002 Examiner Examiner: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

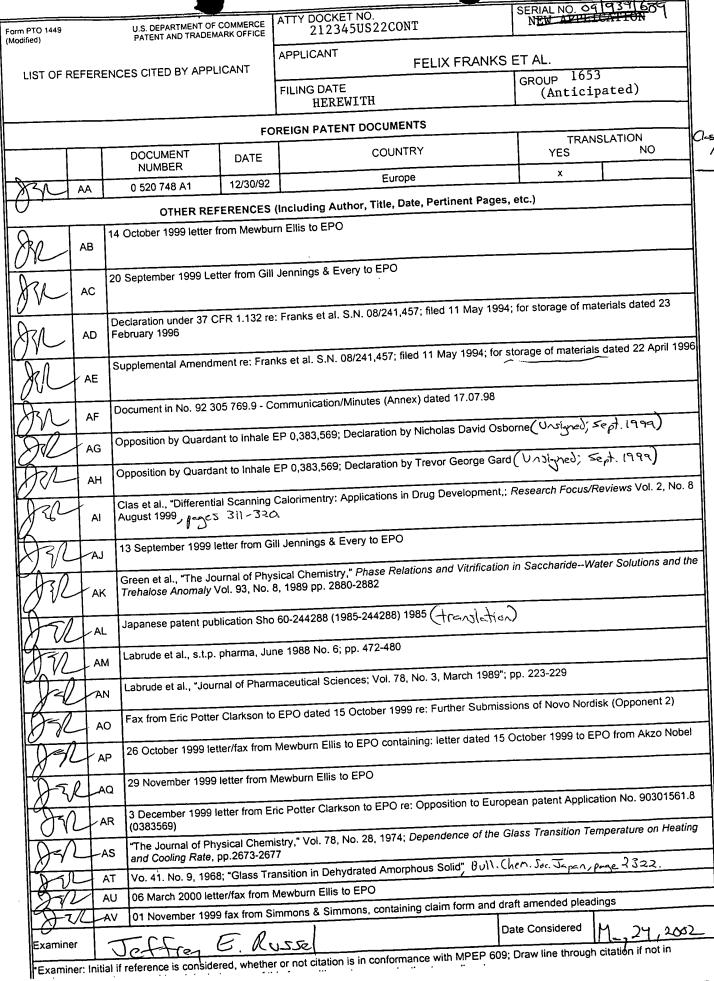
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Jeffrey E. Russel

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